

REMARKS

Applicants will address each of the Examiner's rejections in the order in which they appear in the Office Action.

Claim Objections

The Examiner objects to Claims 21-22 for informalities. In particular, the Examiner states that the preamble language in Claims 21-22 is not considered part of the device. While Applicants have not determined if the Examiner is correct, Applicants have added new Claims 42 and 43 which positively recite these features.

Claim Rejections - 35 USC §112

The Examiner rejects Claims 21-22 under 35 USC §112, second paragraph, as being indefinite.

In particular, the Examiner objects to Claim 22 and states that it is unclear how the radiopaque marker is located in the first lumen and at the same time provides a fluid flow path between the first and second lumens. The Examiner also states that the specification does not support such a claim. Applicants disagree as there is clear support in the specification for this feature.

Specifically, a radiopaque marker located within the first lumen (which receives the treating element) at the distal end of the catheter is described for example in the specification on page 57, lns. 13-19, which describe an intraluminal connector 646 made of platinum/iridium so as to be visible under fluoroscopy. See also Fig. 58C. As can be seen in Fig. 58C, intraluminal connector

646 is located within the first lumen but has an opening to the second lumen. Page 57, lns. 10-13 state that the catheter 647 and its components shown in Figs. 58A-C are identical to that shown in Figs. 42A-42D, except for the catheter connect, the location of the marker and that intraluminal connect may be made of platinum/iridium. The opening of the intraluminal connector to the second lumen is not mentioned as a difference. Page 35, lns. 11-16 state that the seed lumen (i.e. first lumen) and the fluid return lumen (i.e. second lumen) “communicate with one another at the distal end 428 of the catheter 424 through an intraluminal connector 438 (Fig. 42C) which is located in the seed lumen 432.”

Therefore, this claim is not indefinite, and there is clear support in the specification and drawings for the language of the claim.

The Examiner also objects to “the treatment element” in Claim 21, ln. 8. Applicants do not see such a recitation in the claim. Line 8 in this claim recites “the treating element” which has an antecedent basis in line 3 of the claim. In order to clarify this language, Applicants have amended ln. 8 to state “said at least one treating element.” This should overcome the Examiner’s rejection.

Accordingly, for at least the above-stated reasons, it is respectfully requested that the §112 rejection be withdrawn.

Claim Rejections - 35 USC §102

The Examiner also rejects Claims 19-20 under 35 USC 102(e) as being anticipated by Zadini et al. This rejection is respectfully traversed.

In order to advance the prosecution of this application, Applicants have amended Claim 19 to recite “...a connector integral with the proximal end of the catheter including at least one detent

having a transverse tab for securing said connector in the central opening of the transfer device..."

No such detent having a transverse tab is disclosed or suggested in Zadini.

More specifically, while the Office Action refers to reference numeral 16 in Zadini, the Office Action does not state where the alleged detent is shown in Zadini. Applicants note that Figs. 1-4 therein, which show reference numeral 16, show a lever 26 which has an opening 28. Opening 28 is mateable with stud 34 in aperture 32. Zadini does not, however, disclose or suggest a detent with a transverse tab for securing said connector in the central opening of the transfer device, as recited in independent Claim 19.

Therefore, since at least this claimed feature is not disclosed or suggested by the cited reference, Claims 19 and 20 are patentable thereover. Accordingly, it is respectfully requested that this rejection be withdrawn.

Claim Rejections - 35 USC §103

Rejection of Claims 21-22

The Examiner rejects Claims 21-22 under 35 USC §103 over Fiddian-Green and further in view of Bennett et al. This rejection is also traversed.

Claim 21 is directed to a catheter for use in a system for intraluminal treatment of a selected site in a body where the catheter comprises an elongated tube having a proximal end and a distal end, with first and second lumens within the elongated tube and extending between the proximal and distal ends thereof, and the first and second lumens communicating at the distal end.

Such a catheter is not disclosed or suggested by Fiddian-Green or Bennett (which has been merely cited for allegedly having elliptical-shaped lumens).

In the Office Action, the Examiner contends that Fiddian-Green shows these features but does not state where they are allegedly shown. Nonetheless, Applicants disagree with the Examiner's contention.

Fiddian-Green is directed to a remote sensing tonometric catheter which is very different than a catheter for use in a system for intraluminal treatment of a selected site in a body of a patient by at least one treating element, as in the claimed invention. Further, the catheter in Figs. 1-2 of Fiddian-Green appears to have a single lumen extending from the proximal end to the distal end of an elongated tube. The lumens of Figs. 4 are explicitly stated as being noncommunicating with each other (see col. 6, lns. 40-44 in Fiddian-Green). The lumens of Figs. 5 are merely connected with a catheter at the end of the lumen, not in communication with another lumen which extends from the proximal end to the distal end of the elongated tube.

Additionally, Fiddian-Green does not disclose or suggest "at least one radiopaque marker for aligning said distal end and the at least one treating element with the selected site of the body of the patient, said radiopaque marker being located within said first lumen at said distal end and providing a fluid flow path between said first and second lumen," as recited in Claim 22. Instead, Fiddian-Green discloses a radiopaque tungsten plug which is intended to "block" the lumen, or a radiopaque tungsten rod which terminate the end of the lumen. See Col. 7, lns. 20-34 of Fiddian-Green. Hence, the reference does not disclose or suggest a radiopaque marker that provides a fluid path between the first and second lumens.

Therefore, for at least the above-stated reasons, Claims 21 and 22 are not disclosed or suggested by the cited references and are patentable thereover. Accordingly, it is requested that this rejection be withdrawn.

Rejection of Claims 38-39

The Examiner also rejects Claims 38-39 under 35 USC §103 as being unpatentable over Waksman et al. and further in view of Rossemann et al. This rejection is respectfully traversed.

Claim 38 is directed to a catheter for use in an intraluminal treatment system. The catheter has three lumens, one of which is sized to receive a guidewire. Importantly, as specifically recited in the claim, the distal end of this lumen has a lining that resists damage from the guidewire as the catheter is delivered over the guidewire to the treatment site. This is described for example in the specification on page 36, lines 21-26 and is shown in Fig. 42C. As explained therein, for example, such a lining is of a sufficient durometer to resist the guidewire from damaging the distal end of the lumen. Applicants can find no disclosure of such a lining in the cited references and no such disclosure has been pointed out in the Office Action. Accordingly, the rejection of Claim 38 should be withdrawn.

Claim 39 is dependent from Claim 38 and requires the guidewire lumen lining to comprise a blend of a high density polyethylene and a low density polyethylene. The Examiner acknowledges that Waksman does not disclose this feature. The Examiner, however, again cites Rossemann (col. 8, lns. 8-11) as showing this feature. However, the text cited by the Examiner in Rossemann indicates only that one segment of the catheter, the second tubular segment 72, "is a thermoplastic, such as high density polyethylene." However, segment 72 does not even include either a guidewire lumen or a lining of any sort, let alone a guidewire lumen having a lining to prevent damage to the lumen. Further, "high density polyethylene" is not the same as, nor does it suggest, the polyethylene blend of a high density polyethylene and low density polyethylene recited in Claim 39.

In the Examiner's Response to Arguments in the Office Action, the Examiner states that "...applicant claims the lining to be a blend of high and low polyethylene, however gives no reason or evidence in the specification (pages 36-37) why it would be beneficial to use a blend of high and low polyethylene." Applicants disagree. Page 36, lns. 4-14 of the specification of the present application discuss how low density polyethylene allows the catheter to be very flexible, soft and lubricious, but to insure that the catheter is not too soft or pliable, a blend of high and low density may be used.

Hence, the specification clearly shows the benefit of such a blend, and such a blend is not disclosed or suggested in the references.

Therefore, for at least the above-stated reasons, Claims 39 and 40 are not disclosed or suggested by the cited references and are patentable thereover. Accordingly, it is requested that this rejection be withdrawn.

New Claims

In the Examiner's Response to Arguments, the Examiner states that application has not positively recited certain limitations in the claims. Accordingly, Applicants are adding dependent Claims 42 and 43 which positively recite these limitations. It is respectfully submitted that the limitations in these claims are not disclosed or suggested in the cited references, and the claims are patentable thereover.

If any fee is due for these claims, please charge our deposit account 50/1039.

CONCLUSION

Therefore, for at least the above-stated reasons, the present application is now in an allowable condition and should be allowed.

Please charge our deposit account 50/1039 for any further fee for this amendment.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,



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